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510(K) SUMMARY

"This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is _____"

Applicant

Lukens® Medical Corporation
3820 Academy Parkway North NE
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Contact

Mr. Scott Henderson, C.Mfg.E.
Vice President, Development and Engineering

Date

December 16, 1996

Name of Device

Proprietary Name:

Lukens® - PGA (Polyglycolic Acid)
Synthetic Absorbable Surgical
Suture, Coated, Braided U.S.P.

Common or Usual Name:

Polyglycolic Acid Synthetic,
Absorbable Surgical Suture,
Coated, Braided U.S.P.

Classification Name:

Suture, Absorbable, Synthetic,
Polyglycolic Acid

Lukens® - PGA (polyglycolic acid), synthetic absorbable surgical sutures, coated, braided USP manufactured by Lukens® Medical Corporation are equivalent to Dexon II polyglycolic acid, synthetic, absorbable surgical sutures USP with polycaprolate coating system manufactured by Davis & Geck. Lukens® - PGA (polyglycolic acid), synthetic absorbable surgical sutures USP are dyed with D&C Violet No. 2 and are coated with E-Caprolactone.

Testing of suture diameter, suture length, knot-pull tensile strength and needle attachment strength according to methods outlined in USP XXIII demonstrates that Lukens® - PGA (polyglycolic acid), synthetic absorbable surgical sutures meet or exceed USP requirements and are equivalent to Dexon II polyglycolic acid surgical sutures in terms of the above parameters.

Biocompatibility testing showed no evidence of toxicity of Lukens® - PGA (polyglycolic acid), synthetic absorbable surgical sutures, USP.

Implantation studies in animals indicate that Lukens® - PGA retains approximately 50% of its original tensile strength at two week post implantation, with approximately 20% remaining at three weeks. Absorption of Lukens® - PGA absorbable synthetic suture is essentially complete between 60 and 90 days.

The intended use of the device is in general soft tissue approximation and/or ligation including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

12-16-96

Date

Scott Henderson

Scott Henderson, C.Mfg.E.
Vice President, Development and
Engineering

SH-510K